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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/008,062

10/19/2001

David Rizzieri

5405-252

5735

20792

7590

03/28/2005

MYERS BIGEL SIBLEY & SAJOVEC

PO BOX 37428

RALEIGH, NC 27627

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/008,062

Applicant(s)

RIZZIERI ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 05/08/03; 10/05/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Response to Amendment and Arguments*

1. Claims 1-6 and 8-22 are pending.  
Claim 7 has been cancelled.  
Claims 1 and 10 have been amended.  
Claim 22 has been added.  
Claims 1-6 and 8-22 are examined on the merits.
  
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Information Disclosure Statement*

3. Reference 1, RE 38,008 (02/25/2003) cited on the information disclosure statement (IDS) submitted May 8, 2003 has been reviewed, as well as all the references listed on the Supplemental IDS submitted October 5, 2004 duly noted as so and supplied with the instant action.

### *Withdrawn Rejections*

#### *Claim Rejections - 35 USC § 112*

4. The rejection of claims 1-6 and 8-11 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating lymphoma in a subject comprising administering to said subject a radiolabeled chimeric <sup>131</sup>I-81C6,

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does not reasonably provide enablement for any antibody that binds tenascin, as well as a naked 81C6 antibody is withdrawn in light of Applicants arguments and amendment.

### ***Maintained Rejections***

#### ***Claim Rejections - 35 USC § 112***

5. The rejection of claims 4, 12-21 and newly added claim 22 under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials is maintained and newly made.

Applicants assert “<sup>131</sup>I-labeled chimeric 81C6 monoclonal antibody was described in U.S. Patent No. 5,624,659...” and “[c]learly the new use of a known compound does not present the same issues related to the use of a novel compound with respect to enablement.”, see page 6, section B, second paragraph of the Remarks submitted October 5, 2004. Applicants aver, “the specification clearly and explicitly provides guidance that enable one skilled in the art to arrive at the chimeric 81C6 monoclonal antibody”, see Remarks, bridging paragraph of pages 6 and 7. These points of view and arguments have been considered, but found unpersuasive.

“The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily

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available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. *Ex parte Hildebrand*, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).”, see MPEP 2404.01. Applicants are invited to review the patented file and provide evidence that all of the assurances have been met. At this point in prosecution clear and sufficient evidence is not of record and the instant rejection is made and maintained.

### ***Claim Rejections - 35 USC § 103***

7. The rejection of claims 1-6, 8-21 and newly added claim 22 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,624,659 (April 29, 1997/ reference 1 from IDS submitted June 14, 2002), and in view of Rizzieri et al. (Blood 94(10), Part 2, Supplement 1: 4339, Abstract #4339 November 1999/ reference 3 from IDS submitted June 14, 2003) is maintained and newly made. Claim 7 has been cancelled.

Applicants have submitted a 1.132 declaration by Dr. Rizzieri in support of the arguments stated below. Applicants set forth the criteria necessary to establish a *prima facie* case of obviousness, see Remarks, bridging paragraph of pages 7 and 8. Applicants assert, “one of ordinary skill in the art would not have a reasonable

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expectation of success given the unpredictability of successfully treating lymphomas” and “the present invention presents unexpected results with respect to methods of treating lymphoma in a subject...and methods of treating Non-Hodgkin’s lymphoma in a subject...”, see Remarks, page 8, second paragraph; bridging paragraph of pages 8 and 9; and first full paragraph of page 9. These arguments, points of view and the declaration have been carefully reviewed and considered, but found unpersuasive.

Foremost, the declaration is not commensurate in scope with the claims. The Rizzieri declaration focuses on the administration and the implementation of <sup>131</sup>I anti-tenascin *human/mouse chimeric* 81C6 monoclonal antibody in Non-Hodgkin’s lymphoma treatment. However, the claims read on the broadly claimed treatment of lymphoma using a radiolabeled antibody that binds tenascin and a non-chimeric 81C6 monoclonal antibody coupled to <sup>131</sup>I. Accordingly, the Rizzieri declaration does not aid in obviating the instant rejection. Notwithstanding, the declaration does not provide unexpected results that render the claimed invention unobvious.

Secondly, a proper and formidable *prima facie* case of obviousness was established in paragraph 7 of the first action on the merits (FAOM) mailed July 7, 2004 meeting the three basic criteria of a rejection under 35 U.S.C. 103(a). The radiolabeled chimeric monoclonal antibody, <sup>131</sup>I -81C6 or therapeutic antibodies (dosage to the patient in the range of 10mCi to 100mCi) of the disclosed invention are used in the treatment of any tumor that expresses tenascin, see patent, column 2, lines 40-49; bridging paragraph of columns 2 and 3; column 3, line 20-column 4, line 44. And Rizzieri notes non-Hodgkin’s lymphomas have increased angiogenesis and microvessel

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density (MVD) and consequently increased expression of tenascin, see Rizzieri abstract, particularly the last paragraph. Rizzieri plainly "...suggests systemically delivered anti-tenascin antibody may be an effective form of therapy." Based on the combination of these reference teachings one of ordinary skill in the art would have arrived at the claim invention at the time with a reasonable expectation of success. Both references provide suggestion and motivation to establish and arrive at the claimed invention, accordingly the rejection is maintained.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**

Alana M. Harris, Ph.D.  
24 March 2005

